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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/536,597

05/26/2005

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EXAMINER

DRODGE, JOSEPH W

ART UNIT

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1797

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/536,597	Applicant(s) BABA ET AL.	
	Examiner Joseph W. Drodge	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 19 and 28-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 20-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 19 and 28-32 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>05262005</u> . | 6) <input type="checkbox"/> Other: _____ |

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-18 and 20-27, drawn to a microchip on a substrate with branched channel, classified in class 210, subclass 650.
- II. Claim 19, drawn to a microchip with an electrode, classified in class 204, subclass 651
- III. Claims 28-31, drawn to a solvent replacement process, classified in class 210, subclass 634.
- IV. Claim 32, drawn to a mass spectrometry unit, classified in class 422, subclass 82.05.

The inventions are independent or distinct, each from the other because:

Inventions I, II, III and IV are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct if they do not overlap in scope and are not obvious variants, and if it is shown that at least one subcombination is separately usable. In the instant case, subcombination each have separate utility such as with analysis systems employing diverse separation techniques (filtration vs. solvent extraction vs. electrical gradient separation) and diverse assay analysis techniques (selective sorption, mass spectrometry). See MPEP § 806.05(d).

The examiner has required restriction between subcombinations usable together. Where applicant elects a subcombination and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional

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application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

The groups of invention are also restrictable since they are not so linked so as to form a single general inventive concept. The Groups do not contain one or more commonly claimed, corresponding special technical feature (MPEP 1850).

During a telephone conversation with Paul Essatto on April 17, 2008 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-18 and 20-27. Affirmation of this election must be made by applicant in replying to this Office action. Claims 19 and 28-32 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 9 is rejected under 35 U.S.C. 102(e) as being anticipated by Weigl et al patent 6,454,945. Claim 9 discloses a microchip on a substrate (column 11, line 64) comprising a main channel 7 for a liquid sample and plurality of side discharge channels 24, 27, 30 along channel sidewall. Different components pass into the various side channels (column 23, lines 22-45).

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Claims 10-12 and 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilding et al patent 5,304,487. Wilding '487 discloses a microchip (column 3, line 45) on a substrate (appliance at column 3, line 44-45) comprising channels (20a, 20b, 20c) for liquid samples containing components, 1st feed inlet/feeding part for sample 16a, 2nd feed inlets/feeding parts for solvents, reagents and other fluids 16b, 16c (also see column 2, lines 40-60..., column 4, lines 16-17 and column 8, lines 40-45), and sample recovering part 16d at exit/distal end of the device system. The system may contain one or more filters 28 between the feeding parts and filters 80 (column 7, line 45 and 51-55). The channel is branched at fractal detection regions 40 forming a plurality of 2nd branch channels; which may contain lyophilic areas [as in claim 2] that may including sorbing or binding moieties (column 9, lines 24-26 and column 8, lines 46-52). Both the branch channels 40 (column 11, line 33-34 and the downstream detection areas also may contain areas of flow restriction and serially bifurcating flow channels sensitive to changes in flow properties, hence function as damming areas (column 4, lines 10-15).

For claims 10-12 and 16-18, sample feeding part 16A, solvent/other fluid feeding parts 16B and 16C and sample/fluid recovery part 16D are all branched off of main channels 20A, 20B and 20C.

For claims 17 and 18, see pump 52 and application of fluid pressures (column 8, line 36) to apply external forces to the channels.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8 and 20-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al patent 5,304,487 in view of Wilding et al patent 5,637,469, Parce et al patent 6,475,441 and Zanzucchi et al patent 5,846,396. Wilding '487 discloses a microchip (column 3, line 45) on a substrate (appliance at column 3, line 44-45) comprising channels (20a, 20b, 20c) for liquid samples containing components, 1st feed inlet/feeding part for sample 16a, 2nd feed inlets/feeding parts for solvents, reagents and other fluids 16b, 16c (also see column 2, lines 40-60..., column 4, lines 16-17 and column 8, lines 40-45), and sample recovering part 16d at exit/distal end of the device system. The system may contain one or more filters 28 between the

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feeding parts and filters 80 (column 7, line 45 and 51-55). The channel is branched at fractal detection regions 40 forming a plurality of 2nd branch channels; which may contain lyophilic areas [as in claim 2] that may including sorbing or binding moieties (column 9, lines 24-26 and column 8, lines 46-52). Both the branch channels 40 (column 11, line 33-34 and the downstream detection areas also may contain areas of flow restriction and serially bifurcating flow channels sensitive to changes in flow properties, hence function as damming areas (column 4, lines 10-15). For claims 10-12 and 16-18, sample feeding part 16A, solvent/other fluid feeding parts 16B and 16C and sample/fluid recovery part 16D are all branched off of main channels 20A, 20B and 20C.

The claims differ in requiring that a filter is in one of the branched channels and that a damming area is in another of the branched channels. However, Wilding '469, a related patent, teaches in the embodiment of figure 14 for channels 20 and 40 to branch from inlet region 16 towards reaction chambers 22A, and 22B, binding chamber 22C and fractal region 14 (column 15, lines 13-45 with column 11, lines 37-60); Embodiment of figure 5 is stated to include a filter 168 in between an inlet region 16 and reaction chambers (column 14, lines 43-55). Zanzucchi teaches to include damming devices in channels of smaller, capillary dimensions that are coupled to larger chambers (column 4, lines 43-48). Parce, embodiment of figure 3, teaches a capillary bypass channel branching off of a larger channel leading to a dilution chamber such as where reagents may be added (column 11, lines 13-33 and column 11, line 58-20).

It would have been obvious to one of ordinary skill in the arts to have modified the Wilding '487 system by locating filter(s) in a branch channel(s) leading to reaction/detection chamber and damming device(s) in branch channel(s) leading to or associated with bifurcating

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regions , as suggested cumulatively by Wilding '396 and Parce and Zanzucchi, in order to simultaneously react and differently analyze different segments/portions or populations of the fluid sample. Wilding '469 suggest such motivation at column 1, lines 30-36 concerning "complex samples"as does Parce at the Abstract concerning "to perform a number of different manipulations".

For claim 2, the binding and adsorbing channel regions of the references constitute "lyophilic areas".

For other claims, Wilding also disclose "capillary action" for claim 3 (column 3, line 55) and capillary micro-channels having micro-dimensions (column 7, lines 63-67), inflow stoppers or valves for claims 4-5 (column 8, lines 53-54), external forcing means/pumps (column 6, lines 50,59) at claim 6, posts or pillars for claim 7 (column 7, line 67), for claim 8 disclosure of filter being micro-fabricated at column 7, line 51 suggests the filter being a porous membrane or film, for claim 9.

For claim 20, applying of a controlled amount of external force sufficient to fill to hydraulically full volume is disclosed by '487 at column 9, lines 45-47 and see "damming" in Zanzucchi.

For claims 21-27, Zanzucchi teaches plural pumps applying different forces (column 6, lines 43-47); the valves of '487 are effective to start and stop flow of liquid sample and solvent(s) ; and Parce teaches sequential addition of different aqueous and non-aqueous fluids, dilutents and solvents (column 3, line 60-column 4, line 27).

Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al patent 5,304,487 in view of Zanzucchi et al patent 5,846,396. Claims 13-15 differ in requiring

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the feeding part to concern a damming area. Zanzucchi teaches to include damming devices in channels of smaller, capillary dimensions that are coupled to larger chambers (column 4, lines 43-48). It would have been obvious to have incorporated the damming areas of Zanzucchi into the '487 device to better control the starting and stopping of flow of sample, solvent and reagents.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Drodge at telephone number 571-272-1140. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Roy Sample, can be reached at 571-272-1376. The fax phone number for the examining group where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either private PAIR or Public PAIR, and through Private PAIR only for unpublished applications. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JWD
4/19/2008

/Joseph W. Drodge/

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Primary Examiner, Art Unit 1797